K113412

DEC 13 2011

stryker®
Neurovascular

510(k) Summary Of Safety And Effectiveness

Summary Date	December 12, 2011
Submitter Name and Address	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA. 94538
Contact Person:	Rhoda M. Santos Sr. Regulatory Affairs Specialist Phone: 510 413-2269 Fax: 510 413-2588 Email: rhoda.santos@stryker.com
Trade Name:	Target® Detachable Coils
Common Name:	Occlusion Coil, Vascular Occlusion Coil, Neurovascular Occlusion Coil
Classification Name:	Target Detachable Coils are classed as vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively, and are Class II devices (special controls). The special control for the devices is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K093142 (4 February 2010)	Target Detachable Coil and InZone® Detachment System
K102672 (15 October 2010)	Target Detachable Coil
K112385 (15 September 2011)	Target Detachable Coil

Device Description:

Stryker Neurovascular's **Target Detachable Coils** are comprised of four coil types: **Target Coil 360 STANDARD, Target Coil 360 SOFT, Target Coil 360 ULTRA** and **Target Coil HELICAL ULTRA**. All Target Coils are stretch resistant coils. Target Coils incorporate a length of multi-strand material through the center of the coil designed to help resist stretching. Target Coils are designed for use with Stryker Neurovascular's InZone™ Detachment System (sold separately).

Each Target Coil type consists of a platinum-tungsten alloy coil attached to a stainless steel delivery wire. For Target Coil 360 STANDARD, Target Coil 360 SOFT and Target Coil 360 ULTRA coils the distal end of the main coil is formed such that there is a smaller distal loop at the end of the main coil to facilitate placement of the coil. The diameter of the distal loop is 75% that of the rest of the main coil loops.

Stryker Neurovascular's InZone Detachment System is intended for use with all Stryker Neurovascular Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

The modifications described within this Special 510(k) have resulted in 12 new smaller coil sizes to be added to the currently approved Target Helical ULTRA and Target 360 ULTRA coil subtypes. These 12 new UPNs use the same processes as the current Target Detachable Coil products with the only difference being the use of a smaller Platinum (Pt) coil wire diameter of 0.00125in.

Verification Testing:

Verification testing of the modified Target Detachable Coil consisted of the following:

<u>Testing and Assessments performed for modifications that are the subject of this submission</u>

1) Functional Testing to assess mechanical properties impacted by the use of a smaller Platinum (Pt) coil wire diameter of 0.00125in:

a) Main Junction Tensile Test
b) Durability Challenge Test
c) Coil / Catheter Compatibility

2) Assessment of coil migration of smaller coil sizes via Use and Design FMEAs

Accessories:

Target Detachable Coils are packaged within a flushing dispenser coil assembly. The dispenser coil is an accessory item with an attached flushport used to hydrate the coil prior to use.

Indications for Use / Intended Use:

Target Detachable Coils are intended for use in the treatment of intracranial aneurysms and other neuro and peripheral vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Target Coils are indicated for endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Comparison to Predicate Device:

Target Detachable Coils

Stryker Neurovascular's smaller coil sizes Target Detachable Coils have the same intended use/indications for use as the predicate Target Detachable Coils.

Although the smaller coil sizes use a Platinum (Pt) coil wire diameter of 0.00125in to achieve a smaller secondary OD of 1mm and 1.5mm,

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510(k) Summary Of Safety And Effectiveness (cont.)

the modifications do not alter the intended use, indications for use, or the fundamental scientific technology of the predicate devices. Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971 +A1:2003.

Neurovascular has determined the modifications to the predicate devices raise no new questions of safety or effectiveness.

Verification testing has demonstrated the modified Target Detachable Coils are substantially equivalent to the predicate Target Detachable Coils.

Conclusion:

Because the subject modifications do not alter the intended use or indications for use of the predicate devices, or the fundamental scientific technology of the predicate devices; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectivenss, Stryker Neurovascular has determined the modified Target Detachable Coils to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Neurovascular
c/o Ms. Rhoda M. Santos
Senior Regulatory Affairs Specialist
47900 Bayside Parkway
Freemont, CA 94538

DEC 13 2011

Re: K113412
Trade/Device Name: Target Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 17, 2011
Received: November 18, 2011

Dear Ms. Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113412

Device Name: Target Detachable Coils

Indications For Use:

Target Detachable Coils are indicated for the endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Prescription Use X AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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